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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 37

[Docket No. CDC-2014-0011; NIOSH-276]

RIN 0920-AA57

Specifications for Medical Examinations of Coal Miners

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule.

SUMMARY: With this action, the Department of Health and Human Services (HHS), in accordance with a final rule recently published by the Department of Labor's Mine Safety and Health Administration (MSHA), is amending its regulations to establish standards for the approval of facilities that conduct spirometry examinations and to require that all coal mine operators submit a plan for the provision of spirometry and X-ray examinations to all surface and underground coal miners.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be

received by [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by "RIN 0920-AA57," by any of the following methods:

- Internet: Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments will be posted without change to <http://www.regulations.gov> including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to

<http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: A. Scott Laney, Research Epidemiologist, Division of Respiratory Disease Studies, NIOSH, Centers for Disease Control and Prevention, 1095 Willowdale Road, MS HG900.2, Morgantown, WV 26505-2888; (304) 285-5754 (this is not a toll-free number); alaney@cdc.gov.

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I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this rulemaking.

II. Background

A. History of Coal Workers' Health Surveillance Program and Statutory Authority

All mining work generates fine particles of dust in the air. Coal miners who inhale excessive dust are known to develop a group of diseases of the lungs and airways, including silicosis, and Coal Workers' Pneumoconiosis (CWP), and the chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.¹ To address such threats to the U.S. coal mining workforce, the Coal Mine Health and Safety Act was enacted in 1969 (Pub. L. 91-173) and amended by the Federal Mine Safety and Health Act of 1977 (Pub. L. 95-164, 30 U.S.C. 801 et seq.) (Mine Act). The statutes included an enforceable 2 milligrams per cubic meter limit on respirable dust exposure during underground coal mine work (30 U.S.C. 842(b)(2)).² The science available at that time indicated that enforcement of this limit would greatly reduce the development of CWP, but could not ensure that all miners would be protected from developing disabling or lethal disease.

The National Institute for Occupational Safety and Health (NIOSH) Coal Workers' Health Surveillance Program (CWHSP), also authorized by the Mine Act, was established to detect CWP and prevent its progression in individual

¹ Petsonk EL, Parker JE [2008]. Coal workers' lung diseases and silicosis. In: Fishman AP, Elias J, Fishman J, Grippi M, Senior R, Pack A eds. Fishman's Pulmonary Diseases and Disorders. 4th ed. New York: McGraw-Hill, pp. 967-980.

² The Mine Safety and Health Administration (MSHA) published a final rule lowering the existing exposure limit from 2.0 mg/m³ to 1.5 mg/m³ in underground and surface coal mines (79 FR 24814, May 1, 2014).

miners, while at the same time providing information for evaluation of temporal and geographic trends in CWP. The Mine Act grants the HHS Secretary general authority to issue regulations as is deemed appropriate to carry out provisions of the Act and specifically directs that medical examinations for coal miners shall be given in accordance with specifications prescribed by the Secretary (30 U.S.C. 843(a), 957), and grants NIOSH the authority to conduct activities in the field of coal mine health on behalf of the Secretary (30 U.S.C. 951(b)).

To inform each miner of his or her health status, the Act requires that coal mine operators provide each miner who begins work at a coal mine for the first time a chest roentgenogram (hereafter chest radiograph or X-ray) through an approved facility as soon as possible after employment starts. Three years later a miner must be offered a second chest radiograph. If this second examination reveals evidence of CWP, the miner is entitled to a third chest radiograph 2 years after the second. Further, all miners working in a coal mine must be offered a chest radiograph approximately every 5 years. All chest radiographs are to be given in accordance with specifications prescribed by the Secretary of Health and Human Services (30 U.S.C. 843(a)).

Under NIOSH supervision, a summary report based on the readings of the periodic chest radiograph is sent to each participating coal miner, who then has the opportunity to take action to reduce further dust exposure if early dust-induced lung disease is detected. Miners with evidence of CWP have specific rights under 30 CFR Part 90³ to transfer to jobs with lower dust levels (see also 42 CFR 37.7). The combined results of these radiographic examinations of miners (radiographic surveillance) also enable NIOSH to track rates and patterns of CWP among the participating miners, to evaluate whether the implemented dust controls are effective in controlling CWP.

B. Need for rulemaking

On May 1, 2014, the Mine Safety and Health Administration (MSHA) in the Department of Labor published a final rule revising existing health and safety standards in 30 CFR Part 72 to improve health protections for coal miners, including the expansion of requirements for medical surveillance [79 FR 24814]. Section 72.100(a) of the MSHA final rule requires that both underground and surface coal mine operators provide to each miner chest X-rays and spirometry tests using facilities approved by NIOSH, as

³ 30 U.S.C. 843(b).

well as the documentation of occupational history and symptom assessment. Section 72.100(c) of the rule prescribes an initial examination to be provided no later than 30 days after a miner begins employment at a coal mine for the first time, a follow-up exam no later than 3 years after the first, and another no later than 2 years after the second if the second test shows evidence of pneumoconiosis or the spirometry test shows evidence of reduced lung function. In addition to the mandatory exams, § 72.100(b) requires operators to provide each miner with an opportunity to have an X-ray and spirometry examination at least every 5 years. Section 72.100(a)(2) specifies that test results are to be furnished to the Secretary of Health and Human Services, and, at the request of the miner, to the miner's designated physician. Section 72.100(d) of the MSHA final rule requires each coal mine operator to develop a plan for providing X-rays, spirometry, symptom assessment, and occupational history and submit it to NIOSH for approval; operators must also submit a roster of each miner covered by the plan. The MSHA final rule's expansion of that agency's medical surveillance requirements causes HHS to amend its regulations in 42 CFR Part 37 pertaining to the Coal Workers' Health Surveillance Program, thereby expanding the scope of the Program to include coal miners

who work in surface coal mines and adding spirometry testing and symptom assessment for all miners.

C. Statutory Authority

As discussed above, § 203 of the Mine Act directs the HHS Secretary to prescribe time intervals and specifications for the provision of chest X-rays, and standards for the reading, classification, and submission of the films [30 U.S.C. 843(a)]. The Secretary is also authorized to supplement the required X-rays with additional tests as deemed necessary to protect the health and safety of U.S. coal miners.

III. Issuance of an Interim Final Rule with Immediate Effective Date

Rulemaking under the Administrative Procedure Act (APA) generally requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule (5 U.S.C. 553). However, the APA provides for exceptions to its notice and comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public

interest. In accordance with the provisions in 5 U.S.C. 553(b)(3)(B), HHS finds good cause to waive the use of prior notice and comment procedures for this interim final rule (IFR) and to make this action effective immediately.

This IFR amends 42 CFR Part 37 to allow coal miners who work in surface mines to participate in the CWHSP and to expand the Program to include spirometry testing to detect decreased lung function among both underground and surface coal miners. HHS has determined that it is impracticable to use prior notice and comment procedures for this IFR because the effective date of the final rule published by MSHA on May 1, 2014, requiring that NIOSH establish standards to provide spirometry testing, occupational history, and symptom assessment for all underground and surface coal miners, is August 1, 2014. NIOSH is committed to expanding the existing health surveillance program to provide spirometry testing to all coal miners as soon as possible, and believes that it would be contrary to the public interest to delay those individuals' eligibility for inclusion in the program beyond the August 1, 2014 effective date. Thus, HHS is waiving the prior notice and comment procedures in the interest of protecting the health of all coal miners and allowing them to participate in the CWHSP as soon as possible.

Stakeholders were given opportunities to participate in MSHA's proposed rulemaking during seven public hearings held between December 2010 and February 2011. The public comment period for the proposed rule was extended three times since the proposed rule was published on October 19, 2010. MSHA received public comments on the provision related to NIOSH, 30 CFR 72.100, and summarized them in the preamble to the final rule (79 FR 24814, 24927-24929). Commenters were overall supportive of the provision, and MSHA was responsive to those comments that expressed concern or were critical of the measure.

Under 5 U.S.C. 553(d)(3), HHS finds good cause to make this IFR effective immediately. As stated above, in order to protect the health of miners in both underground and surface coal mines, it is necessary that HHS act quickly to amend the existing standards in 42 CFR Part 37 to include surface miners and to establish criteria for the provision of spirometry testing. While amendments to Part 37 are effective on the date of publication of this IFR, they are interim and will be finalized following the receipt of any substantive public comments. (See Section I. Public Participation, above.)

IV. Summary of Interim Final Rule

This interim final rule expands the existing Coal Workers' Health Surveillance Program to provide chest radiographic examinations to miners who work in surface coal mines and establishes new requirements for spirometry testing for all coal miners under existing Part 37 of 42 CFR--Specifications for Medical Examinations of Underground Coal Miners. The title of the Part is amended to read Specifications for Medical Examinations of Coal Miners.

The following is a section-by-section summary which describes and explains the amended provisions of Part 37. The public is invited to provide comment on any aspect of the interim final rule. The amended regulatory text is provided in the last section of this notice.

A. Subpart--Chest Radiographic Examinations

Section 37.1 Scope.

Existing § 37.1 provides the scope of the provisions in Subpart--Chest Radiographic Examinations, and is amended to clarify the purpose of this subpart. Under this subpart, coal mine operators are required to provide X-ray examinations to each current and new coal miner, using medical facilities approved by NIOSH according to the standards established in this subpart.

Section 37.2 Definitions.

Existing § 37.2 contains definitions for terms that appear throughout this subpart and the new Subparts (Subpart--Spirometry Examinations and Subpart--General Requirements). In this section, the definition of "miner" is amended to remove language excluding surface coal miners from coverage under this part. "NIOSH" is amended to update the address of the Division of Respiratory Disease Studies and to reflect that programmatic responsibility is expanded to include medical examinations other than chest radiographs, and to clarify that the program also includes medical surveillance activities. The definition of "operator" is amended to mirror the definition in the Mine Act, and to reflect the inclusion of surface coal miners in the medical examination and surveillance program.

Section 37.3 Chest radiographs required for miners.

Existing § 37.3 requires mine operators to provide miners an opportunity to receive a chest radiograph. This section is amended to remove the word "underground" and remove obsolete dates and examples. The section is also amended to specify that evidence of decreased lung function

demonstrated by a spirometry exam conducted pursuant to § 37.92(b)(2) may trigger a third chest radiograph.

Section 37.4 Plans for chest radiographic examinations.

Existing § 37.4 requires that mine operators submit to NIOSH a plan for chest radiographic examinations, including the beginning and ending dates of the 6-month period for voluntary examinations, and the name and location of the approved X-ray facility or facilities. A form for the documentation of the plan is available on the CWHSP website at

<http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>. This section is removed from this subpart and moved to new § 37.100; specific amendments are discussed below.

Section 37.5 Approval of plans.

Existing § 37.5 outlines the process undertaken by the Secretary of HHS to approve or deny approval of an operator's plan for chest radiographs. This section is removed from this subpart and moved to new § 37.101; specific amendments are discussed below.

Section 37.6 Chest radiographic examinations conducted by the Secretary.

Existing § 37.6 details the conditions under which the HHS Secretary will determine whether to conduct a chest radiographic examination. This section is amended to change the section number to § 37.4 and to replace outdated text with current terminology.

Section 37.7 Transfer of affected miner to less dusty area.

Existing § 37.7 specifies that any miner who exhibits evidence of the development of CWP may transfer from his or her position to another position in the mine with a lower concentration of respirable dust, as compliant with the recently-updated 30 CFR 90.3. This section is removed from this subpart and moved to new § 37.102; specific amendments are discussed below.

Section 37.8 Radiographic examination at miner's expense.

Existing § 37.8 allows that the miner may pay for an X-ray exam himself or herself, and NIOSH will provide the classification and report as if the exam was conducted pursuant to a mine operator's plan. This section is removed from this subpart and moved to new § 37.103; specific amendments are discussed below.

Section 37.40 General provisions.

Existing § 37.40 outlines general provisions for chest X-rays. This section is amended to update the terminology.

Section 37.50 Interpreting and classifying chest radiographs--film.

Existing § 37.50 establishes procedures for the classification of film X-rays. It is amended slightly to update terminology.

Section 37.51 Interpreting and classifying chest radiographs--digital radiography systems.

Existing § 37.51 establishes procedures for the classification of digital X-rays. It is amended slightly to update terminology.

Section 37.52 Proficiency in the use of systems for classifying the pneumoconioses.

Existing § 37.52 establishes the A and B Reader approval programs. This section is amended to update terminology.

Section 37.53 Method of obtaining definitive classifications.

Existing § 37.53 establishes that radiographs will be independently classified by an A Reader and B Reader, or two B Readers, whose classifications must be in agreement as defined in § 37.53(b); if sufficient agreement is lacking, NIOSH shall obtain a third classification. The section is amended to clarify that the section addresses radiographic classifications rather than interpretations, and to update terminology.

Section 37.60 Submitting required chest radiographs and miner identification documents.

Existing § 37.60 establishes the protocol for submitting radiographs to NIOSH. This section is amended to update terminology.

Section 37.70 Review of classifications.

Existing § 37.70(a) establishes that a miner may request that NIOSH reevaluate a CWP interpretation that the miner believes is in error. The section heading and paragraph (a) are amended to replace the words "interpretation" and "interpretations" with "classification" and "classifications." Paragraph (b) is

amended to strike an obsolete reference to standards established in 1978.

B. Subpart--Spirometry Examinations

This subpart is added to Part 37 and establishes standards for spirometry testing for all coal miners, working in both underground and surface mines. The new MSHA rule reduces permissible exposure and increases requirements for dust monitoring, however MSHA acknowledges that in spite of these changes, both surface and underground coal miners remain exposed to hazardous levels of respirable dust that can result in serious and fatal lung diseases. To facilitate early detection of lung injury and thereby provide an additional level of secondary health protection to miners, MSHA now requires that mine operators offer a periodic spirometry examination and symptom assessment, to document respiratory symptoms and lung function, in addition to the previous requirement for providing chest radiographic examinations and obtaining occupational histories.

Section 37.90 Scope

New § 37.90 provides the scope of the provisions in Subpart--Spirometry Examinations, and is amended to clarify

the purpose of this subpart. Under this subpart, coal mine operators are required to provide spirometry examinations to each current and new coal miner, using medical facilities approved by NIOSH according to the standards established in this subpart.

Section 37.91 Definitions

New § 37.91 defines terms used in this subpart. The following new terms are added in this rulemaking: "ATS," "ERS," "facility," "FET," "FEV1," "FEV6," "FVC," "PEF," and "spirometry examination."

Section 37.92 Spirometry examinations required for miners.

New § 37.92 requires coal mine operators to provide all miners an opportunity to receive a spirometry examination. Paragraph (a) of this section specifies the timing and the new content for the miners' ongoing voluntary periodic health examination, as required under the revised MSHA rule. The examination now includes a respiratory assessment and spirometry testing in addition to the previously-required chest radiograph and occupational history. Underground coal mines with previously-existing mine surveillance plans will continue on their already-established schedules for offering periodic health

surveillance. Periodic surveillance schedules for mines that are new to health surveillance, primarily surface mines, will be established by NIOSH in conjunction with approval of mine plans.

Paragraph (b) of this section specifies the timing and content of the respiratory assessment for newly hired miners. To record and provide accurate and timely recognition of important lung functional losses that have been documented to occur during the early years of mining, an initial test is specified within each new miner's first 30 days of employment and a second test after three years of work. If an accelerated loss of function is recognized after three years, then a third test after two additional years is offered to the miner, to determine whether the rate of decline has stabilized. These early examinations are intended to record any early changes in symptoms and spirometry and also provide a more stable baseline for assessing trends in lung function over the miner's subsequent career. The mandatory examinations specified in paragraph (b) are targeted to miners who begin work at a coal mine for the first time. The first spirometry test for experienced miners will be provided when they participate in the next scheduled voluntary examination (as provided in paragraph (a) of this section). For underground coal mines,

examinations will be provided according to the already-established 5 year cycle. For surface mines that are new to surveillance, initial voluntary examinations will be provided over the first 5 years after implementation of expanded surveillance under the IFR at times established by NIOSH when mine plans are approved. This staged approach is necessary to effectively manage services to the more than 90,000 existing U.S. coal miners.

Paragraph (c) explains that NIOSH will notify the miner when he or she is due to receive a second or third examination, and clarifies that a miner must provide written authorization for NIOSH to notify the coal operator of when a third examination is due. However, even if the miner does not complete the examination, the availability of the examination will constitute operator compliance with the plan. This procedure parallels the long established approach to offering third chest radiographs to new miners.

Paragraph (d) states that the availability of spirometry testing must be indicated in the operator's plan required by § 37.100.

Section 37.93 Approval of spirometry facilities.

New § 37.93 establishes standards by which NIOSH will approve facilities that conduct spirometry tests, including

ensuring that spirometry results are of adequate quality, and specifying programmatic approaches to quality assurance and addressing deficiencies. High quality spirometry is essential for the test results to provide information that can be useful in protecting miners' lung health.

Professional organizations have recognized that to optimize the utility of test results, close attention must be paid to a number of important factors. These factors include the type and performance of the testing equipment, the specific training and experience of the test providers, specific testing procedures, programmatic attention to test quality, and the specific approaches to data management and interpretation of results. The approval of facilities that are authorized to provide spirometry under this subpart provides a mechanism to document the specific services offered and the approaches taken by each facility to address these important technical factors.

Paragraph (b) describes the factors considered important in assuring quality spirometry testing for miners covered by this program. Pursuant to the standards established in the 2005 American Thoracic Society (ATS) and European Respiratory Society (ERS) consensus statement, Standardisation of Spirometry, which is incorporated by reference, testing instruments must be capable of

demonstrating calibration, accuracy, and freedom from leaks as required on a daily basis, and results documented. Spirometers must provide an ongoing automatic assessment of test quality during testing, to permit immediate feedback to the technologist and miner. Results of each miner's tests will be provided to NIOSH within 14 calendar days, which will facilitate timely feedback with suggestions for quality improvement. NIOSH may periodically conduct audits to evaluate the quality of spirometry produced by the facility. Records pertaining to the provisions in this section are maintained by NIOSH under CDC/ATSDR Privacy Act System of Records Notice 0920-0149, Morbidity Studies in Coal Mining, Metal and Non-Metal Mining and General Industry. As specified in § 37.96(e), personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative.

Paragraphs (c) and (d) state that if a facility is found to be noncompliant with the regulations in this subpart or if a quality assurance audit finds the facility to be under-performing, the facility will be notified. Facility approvals can be revoked if facilities show

deficiencies that are not rectified in a timely manner, within 60 days of notification.

Paragraph (e) requires the confidentiality of protected information.

Section 37.94 Respiratory assessment form.

New § 37.94 requires that a respiratory assessment form must be completed for each miner upon examination. The form is required in order to provide recording of respiratory symptoms and certain other information relevant to miner lung health using a valid, concise, and consistent format.

Section 37.95 Specifications for performing spirometry examinations.

New § 37.95 establishes standards for the performance of spirometry tests. As discussed in § 37.93, if validated and standardized approaches are not taken, there can be no assurance of providing accurate and consistent test results.

Paragraph (a) of this section requires that persons administering the spirometry testing demonstrate completion of NIOSH-approved spirometry training, and maintain their knowledge by periodically completing an approved refresher course. NIOSH approves sponsors to provide spirometry

training courses. A listing of current courses is maintained on the NIOSH website (<http://www.cdc.gov/niosh>). Private courses may also be available that are not listed on the NIOSH website. Stakeholders are encouraged to contact NIOSH if they have questions about spirometry training opportunities.

Paragraph (b) of this section requires that testing performed under this subpart utilize equipment complying with standards published in the 2005 ATS/ERS Standardisation of Spirometry for size of display, precision, and accuracy as verified by an independent testing laboratory. Requirements for validation checks are established in the ATS Standardization of Spirometry: 1994 Update, which is incorporated by reference. These requirements are met by many of the spirometers that are currently marketed. Although not required, spirometers may also export results electronically if they meet an available industry standard for the file specification, or if the data file content, format, and approach to the transfer is approved by NIOSH.

Paragraph (c) of this section specifies certain required procedures during performance of testing, including testing procedures delineated in the 2005 ATS/ERS Standardisation of Spirometry and the 2010 Standardisation

of Lung Function Testing, authors' replies to readers' comments, which are incorporated by reference. If the spirometer model does not support an approved approach to exporting data files, then certain numerical results must be entered into an electronic Spirometry Results Form (Form CDC/NIOSH (M)2.17) and transmitted to NIOSH, accompanied by images of the three spirometry flow volume and volume time curves reported using a secure internet transfer site.

Section 37.96 Spirometry interpretations, reports, and notifications.

New § 37.96 establishes requirements for the interpretation of spirometry test results, as well as specifications for the content, deletion, and transmission of test reports. This section also addresses the notification of miners of the test results and their confidentiality. Paragraph (a) of this section requires qualified health care professionals at the facilities to interpret results using a standardized approach, described in the 2005 ATS/ERS Interpretative Strategies for Lung Function Tests, and the 2014 Official ATS Standards: Spirometry in the Occupational Setting, which are incorporated by reference.

Paragraph (b) specifies the content of spirometry test reports and the deletion of files and forms associated with the examination. The requirement for deletion of these files and forms is included to help protect the confidentiality of this personal information.

Paragraph (c) requires that findings are communicated to the miner or the miner's designated physician.

Paragraphs (d) and (e) of this section further specify the responsibilities of approved facilities to assure the confidentiality of all personal identifying information associated with testing performed under this subpart, to transfer all completed forms and spirometry results to NIOSH, and after NIOSH has indicated successful receipt of the data, to delete the records, to the extent feasible. Requirements for the transmission of spirometry data files are specified in the 2005 ATS/ERS Standardisation of Spirometry, which is incorporated by reference. NIOSH will send complete reports of spirometry examinations to the miner, along with any recommendations for follow-up.

Section 37.97 Standards incorporated by reference.

New § 37.97 identifies standards incorporated by reference throughout this subpart.

C. Subpart--General Requirements

This new subpart establishes general requirements for all surface and underground coal mine operators.

Section 37.100 Coal mine operator plan for medical examinations.

New § 37.100 requires that all coal mine operators submit a plan for providing miners with X-ray and spirometry exams, occupational histories, and respiratory assessment.

Paragraph (a)(1) of this section specifies that on or after August 1, 2014, a person becoming a coal mine operator, for example by purchasing an existing mine or developing a new mine, or a coal mine operator without an approved plan must submit a plan within 60 days that provides for chest radiographs and occupational histories.

Paragraph (a)(2) states that all operators with approved examination plans providing only for chest radiographs and occupational histories, will be notified by MSHA when they are required to submit an amended examination plan that includes spirometry and respiratory assessments. Such plans must be submitted to NIOSH within 60 days of that MSHA notification. New plans submitted from this time forward will provide covered workers with chest

radiographs, spirometry tests, respiratory assessments, and occupational histories as specified in the IFR.

Paragraph (b) lists the required components of the operator's plan, including the identification of the medical facilities that will conduct the spirometry and X-ray exams, and the approximate dates and times during which the test will be provided. The plan must also provide assurances that operators will not solicit medical results or findings from miners; will instruct facilities about management of data as specified; and that examinations will be made at no charge to the miner.

Paragraph (c) of this section specifies that operators may provide for alternate medical testing facilities and personnel.

Paragraph (d) specifies that a change of operators does not affect the existing plan.

Paragraph (e) specifies that the operator must advise NIOSH of any change in its plan and that the change is subject to the same review and approval as the original plan.

Paragraph (f) specifies requirements for notifying employees of proposed mine plans or proposed changes to mine plans.

Paragraph (g) notes requirements for periodic resubmission of plans.

Section 37.101 Approval of plans.

New § 37.101 establishes that the operator's plan will be approved by NIOSH if it is found to meet the requirements in this subpart. Where an approval is denied, NIOSH will give notice in writing to the operator, who may amend the plan.

Section 37.102 Transfer of affected miner to less dusty area.

New § 37.102 establishes the evidentiary threshold required for a miner who is thought to be developing pneumoconiosis related to coal mine dust exposure to request transfer to a less dusty environment in the mine.

Section 37.103 Medical examinations at miner's expense.

New § 37.103 states that any miner who wishes to obtain an X-ray or spirometry exam at his or her own expense may do so. NIOSH will provide an interpretation and report as if the results were submitted under an operator's plan.

V. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim final rule is not being treated as a "significant" action under E.O. 12866. It amends existing regulations in 42 CFR Part 37 to add new requirements on mine operators to provide symptom assessment and spirometry testing for the surveillance of decreased lung function to all coal miners, and to extend existing requirements to provide chest X-rays and occupational histories for underground coal miners to surface coal mine operators. The amendments to Part 37 described in this action are made pursuant to the MSHA final rule published on May 1, 2014 (79 FR 24814) which requires the expansion of the scope and content of current respiratory health surveillance, and are part of that agency's efforts to reduce lung disease among

coal miners. MSHA estimated this expanded respiratory health surveillance would result in annualized costs to underground mines of \$173,500 per year and for surface mines of \$559,900 per year. The Department of Labor has determined that its rule fulfills the requirements of E.O. 12866 for this rule and provides estimates of the aggregate cost of benefits and costs of expanding the CWHSP administered by NIOSH under its rule (see MSHA's Regulatory Economic Analysis at <http://www.msha.gov/rea.htm>).

The rule does not interfere with State, local, or tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. This rule establishes requirements for the provision of chest X-rays and spirometry tests to all coal miners, and sets standards for the approval of testing facilities and transmission of test data.

The potential impact on small businesses has been analyzed by MSHA, in the Regulatory Economic Analysis

published in support of that agency's May 1, 2014 final rule (see <http://www.msha.gov/REGS/REA/CoalMineDust2010.pdf>). This interim final rule does not impose any new requirements on small radiographic or spirometry facilities that participate in the Coal Workers' Health Surveillance Program administered by NIOSH under 42 CFR Part 37. This interim final rule will not impose a significant economic burden on small coal mines. Accordingly, HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 et seq., requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. This interim final rule continues to impose the same information collection requirements as under the existing rule, including the submission of the following forms:

- Chest Radiograph Classification Form [CDC/NIOSH (M)2.8]

- Miner Identification Document [CDC/NIOSH (M)2.9]
- Coal Mine Operator's Plan [CDC/NIOSH (M)2.10]
- Radiographic Facility Certification Document
[CDC/NIOSH (M)2.11(E)]
- Physician Application for Certification [CDC/NIOSH
(M)2.12(E)]
- Consent, Release, and History Form [CDC/NIOSH (M)2.6]

These forms were previously approved by OMB for data collected under the National Coal Workers' X-Ray Surveillance Program (CWXSP) - Federal Mine Safety and Health Act of 1977 (42CFR37) (OMB Control No. 0920-0020, exp. May 31, 2017), although the addition of surface coal miners to the CWHSP increases the burden.

The expansion of the CWHSP in accordance with this rulemaking will result in the participation of additional coal miner operators, coal miners, and physicians. The provisions in this interim final rule that contain data collection requirements are:

Section 37.100 Coal mine operator plan for medical examinations. Every operator must submit a mine plan (Form CDC/NIOSH (M)2.10 or (M)2.18) every 3 to 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the chest radiographic examination. Completing this form with all requested information

(including a roster of current employees) is estimated to take approximately 30 minutes.

Section 37.43 Approval of radiographic facilities that use film and Section 37.44 Approval of radiographic facilities that use digital radiography systems. X-ray facilities seeking NIOSH approval to provide miner X-rays under the CWHSP must complete an approval packet, including a Radiographic Facility Certification Document (Form CDC/NIOSH (M)2.11). The forms associated with this approval process require approximately 30 minutes for completion. This form has been revised since the last OMB approval. A space has been added for the room number in which each X-ray unit listed for approval is located. This is needed to identify the location of the X-ray unit in hospitals and distinguish between units that may be identical except for the serial number. The serial number is not readily visible, so this will aid in identifying individual X-ray units. No additional burden to the facility is anticipated.

Section 37.20 Miner identification document. Miners who elect to participate in the CWHSP must fill out the Miner Identification Document (Form CDC/NIOSH (M)2.9) which requires approximately 20 minutes to complete. This document records demographic and occupational history, as well as information required under the regulations from

X-ray facilities in relation to coal miner examinations. In addition to completing this form, acquiring the chest image takes approximately 15 minutes.

Section 37.50 Interpreting and classifying chest radiographs--film and Section 37.51 Interpreting and classifying chest radiographs--digital radiography systems.

NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO), in the determination of pneumoconiosis among coal miners.

Physicians (A and B Readers) fill out the Chest Radiograph Classification Form (Form CDC/NIOSH (M)2.8) regarding their classification of the X-rays (each X-ray has at least two separate classifications). As stated above, this form has been revised since the last OMB approval. Based on prior practice it takes the physician approximately 3 minutes to complete each form. No additional burden to the physician is anticipated.

Section 37.52 Proficiency in the use of systems for classifying the pneumoconiosis. Physicians taking the B Reader Examination are asked to complete the Physician Application for Certification (Form CDC/NIOSH (M)2.12), which is a registration form that takes approximately 10 minutes to complete. This form has been revised since the last OMB approval. No additional burden to the physician is

anticipated.

Section 37.93 Approval of spirometry facilities.

Spirometry facilities seeking NIOSH approval to provide spirometry examinations under the CWHSP must complete an approval packet, including a Spirometry Facility Certification Document (Form CDC/NIOSH (M)2.14). The form and gathering supporting documentation associated with this approval process requires approximately 30 minutes to complete.

Section 37.95 Specifications for performing spirometry examinations. Clinic personnel are required to complete the Spirometry Pre-Test Checklist form (Form CDC/NIOSH (M)2.15) for each miner prior to administering the spirometry test. This information is used by the clinic personnel to determine if the miner can perform the spirometry test safely and identify any factors that may affect the spirometry results. Completion of the form will take approximately 5 minutes.

Section 37.96 Spirometry interpretations, reports, and notifications. Spirometry facilities that do not submit spirometry results using a NIOSH-approved electronic database will submit the Spirometry Results Form (Form CDC/NIOSH (M)2.17) for each miner. This information allows NIOSH to identify the miner, conduct quality assurance

audits, and interpret results. It will take approximately 10 minutes to complete the form.

Section 37.96 Spirometry interpretations, reports, and notifications. Spirometry facilities must submit the Spirometry Notification Form (Form CDC/NIOSH (M)2.16) to NIOSH upon completion of a spirometry examination. Miners must fill out their mailing address for notification of results; this will take approximately 2 minutes. The remainder of the information documents that the facility completed and transmitted the required components of the spirometry examination. Completion of the entire form will require 10 minutes.

Section 37.94 Respiratory assessment form. The Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) is designed to assess respiratory symptoms and certain medical conditions and risk factors. Completion of the entire form will require 5 minutes.

Section 37.202 Payment for autopsy. The Pathologist Invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this

statement to the standard invoice that they routinely use.

Section 37.203 Autopsy specifications. The pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports are variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

There is no additional recordkeeping burden associated with the quality assurance programs referenced in § 37.43 Approval of radiographic facilities that use film, § 37.44 Approval of radiographic facilities that use digital radiography systems, and § 37.93 Approval of spirometry facilities, because these provisions reflect standard industry practice and do not impose any new recordkeeping requirements.

HHS estimates that the paperwork burden associated with this rulemaking will be 16,358 hours.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per	Average Burden/Response	Total Burden
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			Respondent	(hours)	(hours)
Coal mine operators	Form 2.10 and Form 2.18	958	1	30/60	480
X-ray facility supervisor	Form 2.11	40	1	30/60	20
Coal miner	Form 2.9	10,383	1	20/60	3,461
B Reader physicians	Form 2.8	200	104	3/60	1,040
Physicians taking B reader examination	Form 2.12	50	1	10/60	8
Next-of-kin of deceased miner	Form 2.6	5	1	15/60	1
Spirometry facility employee	Form 2.13	10,383	1	5/60	865
Spirometry facility supervisor	Form 2.14	200	1	30/60	100
Spirometry technician	Form 2.15	10,383	1	5/60	865
Spirometry facility employee	Form 2.16	10,383	1	10/60	1,730
Spirometry technician	Form 2.17	10,383	1	10/60	1,730
X-ray - Coal Miners	No form required	10,383	1	15/60	2,596
Spirometry Test - Coal Miners	No form required	10,383	1	20/60	3,461
Pathologist - Invoice	No form required	5	1	5/60	0.4
Pathologist - Report	No form required	5	1	5/60	0.4
Total					16,358

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the Department will report the promulgation of this rule to Congress prior to its effective date. The report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 et seq.) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or tribal governments in the aggregate, or by the private sector. For 2014, the inflation-adjusted threshold is \$152 million.

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. Chest radiograph classifications that result in a finding of pneumoconiosis may be an element in claim processing and adjudication conducted by DOL's Black Lung Compensation Program. This interim final rule affects radiographs submitted to DOL for the purpose of reviewing and administering those claims. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of

this rule on children. HHS has determined that the rule would have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law No. 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the interim final rule consistent with the Federal Plain Writing Act guidelines.

VI. Interim Final Rule

List of Subjects in 42 CFR Part 37

Chronic Obstructive Pulmonary Disease, Coal Workers' Pneumoconiosis, Incorporation by Reference, Lung diseases, Mine safety and health, Occupational safety and health, Part 90 miner, Part 90 transfer rights, Pneumoconiosis, Respiratory and pulmonary diseases, Silicosis, Spirometry, Surface coal mining, Underground coal mining, X-rays.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 37 as follows:

PART 37--SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF COAL MINERS

1. The authority citation for part 37 continues to read as follows:

Authority: Sec. 203, 83 Stat. 763 (30 U.S.C. 843), unless otherwise noted.

Subpart--Chest Radiographic Examinations

2. Revise the heading of the first subpart to read as set forth above.

3. Revise § 37.1 to read as follows:

§ 37.1 Scope.

Under this subpart, coal mine operators are required to provide radiographic examinations to each current and new coal miner, using medical facilities approved by NIOSH in accordance with standards established in this subpart.

4. Amend § 37.2 by revsing the definitions of "miner", "NIOSH" and "operator" to read as follows:

§ 37.2 Definitions.

* * *

Miner means any individual working in a coal or other mine.

NIOSH means the National Institute for Occupational Safety and Health (NIOSH), located within the Centers for Disease Control and Prevention (CDC). Within NIOSH, the Division of Respiratory Disease Studies (DRDS), 1095 Willowdale Road, Morgantown, WV 26505, formerly called the Appalachian Laboratory for Occupational Safety and Health, is the organizational unit that has programmatic responsibility for the medical examination and surveillance program.

* * * * *

Operator means any owner, lessee, or other person who operates, controls, or supervises a coal or other mine or

any independent contractor performing services or construction at such mine.

* * * * *

5. Revise § 37.3 to read as follows:

§ 37.3 Chest radiographs required for miners.

(a) Voluntary examinations. Every operator must provide to each miner who is employed in or at any of its coal mines and who was employed in coal mining prior to December 30, 1969, or who has completed the required examinations under § 37.3(b) an opportunity for a chest radiograph at no cost to the miner in accordance with this subpart:

(1) NIOSH will notify the operator of each coal mine of a period within which the operator may provide examinations to each miner employed at its coal mine. The period must begin no sooner than October 15, 2012, and end no later than a date specified by NIOSH separately for each coal mine. Within the period specified by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.101.

(2) For all voluntary examinations, NIOSH will notify the operator of each coal mine when sufficient time has elapsed since the end of the previous 6-month period of examinations. NIOSH will specify to the operator of each

mine a period within which the operator may provide examinations to its miners employed at its coal mine. The period must begin no sooner than 3.5 years and end no later than 4.5 years subsequent to the ending date of the previous 6-month period specified for a coal mine either by the operator on an approved plan or by NIOSH if the operator did not submit an approved plan. Within the period specified by NIOSH for each mine, the operator may select a 6-month period within which to provide examinations in accordance with a plan approved under § 37.101.

Example: NIOSH finds that examinations were previously provided to miners employed at mine Y in a 6-month period from July 1, 2013, to December 31, 2013. NIOSH notifies the operator at least 3 months before July 1, 2017 (3.5 years after December 31, 2013) that the operator may select and designate on its plan the next 6-month period within which to offer examinations to its miners employed at mine Y. The 6-month period must be scheduled between July 1, 2017, and July 1, 2018 (between 3.5 and 4.5 years after December 31, 2013).

(3) Within either the next or future period(s) specified by NIOSH to the operator for each of its coal mines, the operator of the coal mine may select a different 6-month period for each of its mines within which to offer examinations. In the event the operator does not submit an approved plan, NIOSH will specify a 6-month period to the operator within which miners must have the opportunity for examinations.

(b) Mandatory examinations. Every operator must provide to each miner who begins working in or at an underground coal mine for the first time after December 30, 1969 or in or at a surface coal mine for the first time after August 1, 2014:

(1) An initial chest radiograph, as soon as possible, but in no event later than 30 days after commencement of employment or within 30 days of approval of a plan to provide chest radiographs. An initial chest radiograph given to a miner according to former regulations for this subpart prior to August 1, 2014 will also be considered as fulfilling this requirement.

(2) A second chest radiograph, in accordance with this subpart, 3 years following the initial examination if the miner is still engaged in coal mining. A second radiograph given to a miner according to former regulations under this subpart prior to August 1, 2014 will be considered as fulfilling this requirement.

(3) A third chest radiograph 2 years following the second chest radiograph if the miner is still engaged in coal mining and if the second radiograph shows evidence of category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), category 3 (3/2, 3/3, 3/+) simple pneumoconioses, or complicated pneumoconioses (ILO Classification) or if the

second spirometry examination specified in § 37.92(b)(2) shows evidence of decreased lung function to the extent specified in § 37.92(b)(3).

(c) Notification. NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, NIOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator must not state the medical reason for the examination or that it is the third examination in the series. If the miner is notified by NIOSH that the third mandatory examination is due and the operator is not so notified, availability of the radiographic examination under the NIOSH-approved operator's plan will constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner refuses to take the examination.

(d) Availability of chest radiographs. The opportunity for chest radiographs to be made available by an operator for purposes of this subpart must be provided in accordance with a plan that has been submitted and approved in accordance with this subpart.

§ 37.4 [Removed]

6. Remove § 37.4.

§ 37.5 [Removed]

7. Remove § 37.5.

§ 37.6 [Redesignated as § 37.4]

8. Redesignate § 37.6 as § 37.4 and in the section heading and in paragraph (a)(1) remove the word "roentgenographic" and add in its place "radiographic".

§ 37.7 [Removed]

9. Remove § 37.7.

§ 37.8 [Removed]

10. Remove § 37.8.

11. Amend § 37.10 in paragraph (a) by revising the first sentence to read as follows:

§ 37.10

(a) Certain material is incorporated by reference into this subpart, Subpart--Chest Radiographic Examinations, with the approval of the Director of the Federal Register

under 5 U.S.C. 552(a) and 1 CFR part 51. * * *

* * * * *

§ 37.40 [Amended]

12. Amend § 37.40 in paragraph (b) by removing the word "Roentgenographic" and adding in its place "Radiographic".

§ 37.50 [Amended]

13. Amend § 37.50 in paragraph (a) by removing the phrase "Roentgenographic Interpretation" and adding in its place "Chest Radiograph Classification".

§ 37.51 [Amended]

14. Amend § 37.51 in paragraph (b) by removing the phrase "Roentgenographic Interpretation" and adding in its place "Chest Radiograph Classification".

§ 37.52 [Amended]

15. Amend § 37.52 in paragraph (a)(2)(i) by removing the phrase "Roentgenographic Interpretation" and adding in its place "Radiographic Interpretation".

§ 37.53 [Amended]

16. Amend § 37.53 by removing the terms

"interpreted", "interpretation", and "interpretations" and adding in their place "classified", "classification", and "classifications", respectively, wherever they occur, and in paragraph (b) by removing the phrase "Roentgenographic Interpretation" and adding in its place "Chest Radiograph Classification".

§ 37.60 [Amended]

17. Amend § 37.60 in the section heading and paragraphs (a) introductory text and (a)(1) by removing the phrase "Roentgenographic Interpretation" and add in its place "Chest Radiograph Classification".

§ 37.70 [Amended]

18. Amend § 37.70 in paragraph (a) by removing the terms "interpretation" and "interpretations" and adding in their place "classification" and "classifications", respectively, wherever they occur, and in paragraph (b) by removing the phrase "made subsequent to August 1, 1978,".

19. Add a subpart, titled Spirometry Examinations, after the undesignated center heading "Review and Availability of Records" to read as follows:

Subpart--Spirometry Examinations

Sec.

- 37.90 Scope.
- 37.91 Definitions.
- 37.92 Spirometry examinations required for miners.
- 37.93 Approval of spirometry facilities.
- 37.94 Respiratory assessment form.
- 37.95 Specifications for performing spirometry examinations.
- 37.96 Spirometry interpretations, reports, and notifications.
- 37.97 Standards incorporated by reference.

§ 37.90 Scope.

Under this subpart, coal mine operators are required to provide spirometry examinations to each current and new coal miner, using medical facilities approved by NIOSH in accordance with standards established in this subpart.

§ 37.91 Definitions.

Definitions provided in § 37.2 will have the same meaning in this subpart. Any term defined in the Federal Mine Safety and Health Act of 1977 and not defined in § 37.2 or this section will have the meaning given it in the Act. As used in this subpart:

ATS means American Thoracic Society.

ERS means European Respiratory Society.

Facility means a facility or organization licensed to provide health care by the State or Territory in which

services are provided, such as a hospital, a clinic, or other provider that performs spirometry examinations.

FET means forced expiratory time, which is the time from the beginning of exhalation (the back-extrapolated "time zero") to the end of the expiratory maneuver.

FEV1 means forced expiratory volume in the first second, which is the volume of air that can forcibly be blown out in one second, after full inspiration.

FEV6 means forced expiratory volume in the first six seconds, which is the volume of air that can forcibly be blown out in six seconds, after full inspiration.

FVC means forced vital capacity, which is the volume of air that can forcibly be blown out after full inspiration.

PEF means peak expiratory flow, which is the maximal airflow during a forced expiratory maneuver.

Spirometry examination means a pulmonary function test that measures expiratory volume and airflow rates and may determine the presence and severity of lung function impairments, if such are present.

§ 37.92 Spirometry examinations required for miners.

(a) Voluntary examinations. Each operator must provide to all miners who are employed in or at any of its coal mines the opportunity to have a spirometry examination and

a respiratory assessment at no cost to the miner at least once every 5 years in accordance with this subpart. The examinations will be available during a 6-month period that begins no less than 3.5 years and not more than 4.5 years from the end of the last 6-month period.

(b) Mandatory examinations. Every operator must provide to each miner who begins work in or at a coal mine for the first time on or after August 1, 2014, a spirometry examination and respiratory assessment at no cost to the miner in accordance with this subpart.

(1) Initial spirometry examination. An initial spirometry examination and respiratory assessment will be provided to all miners who begin work in or at a coal mine for the first time on or after August 1, 2014 within the first 30 days of their employment or within 30 days of approval of a plan to provide spirometry examinations.

(2) Second examination. A follow-up second spirometry examination and respiratory assessment will be provided to the miner no later than 3 years after the initial spirometry examination if the miner is still engaged in coal mining.

(3) Third examination. A third spirometry examination and respiratory assessment will be provided no later than 2 years after the examinations in paragraphs § 37.3(b)(2) and

paragraph (b)(2) of this section if the chest radiograph shows evidence of pneumoconiosis as defined in § 37.3(b)(3) or if the second spirometry test results demonstrate more than a 15 percent decline in the value of percent predicted FEV1 since the initial test. Percent predicted FEV1 will be calculated according to prediction equations published in Spirometric Reference Values from a Sample of the General U.S. Population, American Journal of Respiratory and Critical Care Medicine, 159(1):179-187, January 1999, (incorporated by reference, see § 37.97). A correction factor to Caucasian reference values will be applied when testing individuals of Asian descent as specified in the ATS Technical Standards: Spirometry in the Occupational Setting, p. 987 (incorporated by reference, see § 37.97).

(c) Notification. NIOSH will notify the miner when he or she is due to receive the second or third mandatory examination under (b) of this section. Similarly, NIOSH will notify the coal mine operator when the miner is to be given a second examination. The operator will be notified concerning a miner's third examination only with the miner's written consent, and the notice to the operator must not state the medical reason for the examination or that it is the third examination in the series. If the miner is notified by NIOSH that the third mandatory

examination is due and the operator is not so notified, availability of the spirometry examination under the NIOSH-approved operator's plan will constitute the operator's compliance with the requirement to provide a third mandatory examination even if the miner does not take the examination.

(d) Availability of spirometry testing. The opportunity for spirometry to be available for purposes of this subpart must be indicated in an operator's plan that has been submitted and approved in accordance with this subpart.

§ 37.93 Approval of spirometry facilities

(a) Facilities seeking approval to provide the spirometry examinations specified under this subpart must have the ability to provide spirometry of high technical quality. Thus, NIOSH-approved facilities must meet the requirements specified in this subpart for the following activities: training technicians to perform the tests; conducting spirometry tests using equipment and procedures that meet required specifications; collecting the respiratory assessment form; transmitting data to NIOSH; and communicating with miners as required for scheduling, testing, and notification of results. Facilities seeking approval may apply to NIOSH using the Spirometry Facility

Certification Document (Form CDC/NIOSH (M)2.14), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>.

(b) Spirometry quality assurance. A spirometry quality assurance program must be in place to minimize the rate of invalid test results. This program must include all of the following components:

(1) Instrument calibration checks. Testing personnel must fully comply with the 2005 ATS/ERS Standardisation of Spirometry guidelines for instrument calibration check procedures, pp. 322-323, including Table 3 (incorporated by reference, see § 37.97). Calibration check procedures must include daily (day of testing) leak and volume accuracy checks and linearity checks according to the frequency established by the 2005 ATS/ERS guidelines. Instrument calibration check records must be maintained by the facility and available for inspection.

(2) Automated maneuver and test session quality checks. The spirometer software must automatically perform quality assurance checks on expiratory maneuvers during each spirometry testing session. Messages must alert the technician to maneuver acceptability errors and test session non-repeatability. Each spirometry test session

must have the goal of obtaining 3 acceptable with 2 repeatable forced expiratory maneuvers, as defined by the 2005 ATS/ERS Standardisation of Spirometry, p. 325 (incorporated by reference, see § 37.97).

(3) Ongoing monitoring of test quality. Facilities must submit spirometry results to NIOSH within 14 calendar days of testing as specified in § 37.95(d) to permit NIOSH to monitor test quality and provide a report to the miner. NIOSH may provide feedback to the appropriate technician(s) along with suggestions for improvement.

(4) Quality assurance audits. NIOSH may periodically conduct audits to review examinations submitted by approved facilities and assess the quality of spirometry provided. Such audits may include a review of all spirometry examination data obtained during a specified time period or review of spirometry test data collected over time on selected miners.

(c) Noncompliance. If NIOSH determines that a facility is not compliant with the policies and procedures specified in this subpart, or determines as the result of a quality assurance audit specified in this section that a facility is not performing spirometry examinations of adequate quality, the facility will be notified of the deficiency.

The facility must promptly make appropriate arrangements for the deficiency to be rectified.

(d) Revocation of approval. If a facility fails to rectify deficiencies within 60 days of notification, NIOSH approval of the facility may be revoked. An approval which has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted by the facility to prevent a recurrence.

(e) Maintenance of records. In conducting medical examinations pursuant to this part, physicians and radiographic facilities must maintain the results and analyses of these examinations (including any hard copies or digital files containing individual data, interpretations, classifications, and images) in a manner consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

§ 37.94 Respiratory assessment form.

As part of the spirometry examination and concurrent with it, personnel at the facility must complete a Respiratory Assessment form (Form CDC/NIOSH (M)2.13), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, for the miner.

§ 37.95 Specifications for performing spirometry examinations.

(a) Persons administering the spirometry examination. Each person administering spirometry examinations must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses, identified on the NIOSH website at <http://www.cdc.gov/niosh/>. A copy of the certificate of completion from a NIOSH-approved spirometry training or refresher course, with validation dates printed on the document, must be available for inspection. NIOSH will assign each person administering spirometry examinations a unique identification number, which must be entered into the spirometry system computer whenever instrument quality assurance or miner testing is done or on the Spirometry Results form (Form CDC/NIOSH (M)2.17), available at

<http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>.

(b) Spirometer specifications. Spirometry testing equipment must meet the 2005 ATS/ERS Standardisation of Spirometry specifications for spirometer accuracy and precision and real-time display size and content, pp. 331-333, including Table 2 on p. 322 and Table 6 on p. 332 (incorporated by reference, see § 37.97). Facilities must make available for inspection written verification from a third-party testing laboratory (not the manufacturer or distributor) that the model of spirometer being used has successfully passed its validation checks as required by the Standardization of Spirometry; 1994 Update protocol, Appendix B pp. 1126-1134, including Table C1 (incorporated by reference, see § 37.97). Facilities may request such documentation from spirometer manufacturers. For each forced expiratory maneuver submitted for a miner under this part, the spirometry data file must retain a record of the parameters defined in the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see § 37.97). Spirometers that provide electronic transfer of spirometry data results files must use the format, content, and data structure specified by

the 2005 ATS/ERS Standardisation of Spirometry, p. 335, or a procedure for data transfer that is approved by NIOSH.

(c) Spirometry examination procedures. Administration of spirometry examinations must include the following:

(1) Pre-test checklist. A short Spirometry Pre-Test Checklist (Form CDC/NIOSH (M) 2.15), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be administered prior to each spirometry examination to identify possible contraindications to testing, or factors that might affect results.

(2) Respiratory assessment. A standardized Respiratory Assessment form (Form CDC/NIOSH (M) 2.13), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be completed at the initial spirometry examination and repeated at each spirometry examination.

(3) Collection of anthropometric and demographic information. The miner's standing height must be measured in stocking feet using a stadiometer (or equivalent device) each time the miner has a spirometry test. The miner's weight must also be measured (in stocking feet). The miner's birth date, race, and ethnicity must also be recorded. These data will be entered into the spirometry

system computer and transmitted with the spirometry data file. For facilities with spirometers that do not permit electronic transfer of data files as specified in § 37.96(d), the Spirometry Results form (Form CDC/NIOSH (M) 2.17), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, will be completed for each miner tested, and will report the numerical results of the highest and second highest results for the FVC and FEV1 and the highest PEF from at least three maximal, acceptable expiratory maneuvers (also called trials), as well as the FEV6 derived from those maneuvers reported.

(4) Examination. The spirometry examination will be conducted in accordance with test procedures defined in the 2005 ATS/ERS Standardisation of Spirometry, pp. 323-326, and the Standardisation of Lung Function Testing, Replies to Readers, pp. 1496-1498 (both incorporated by reference, see § 37.97).

(i) The technician must be able to view real-time testing display screens as specified in the 2005 ATS/ERS Standardisation of Spirometry, p. 322 (incorporated by reference, see § 37.97).

(ii) A miner will be tested in the standing position, but may be seated if he or she experiences lightheadedness

or other signs or symptoms that raise a safety concern relating to the standing position during the spirometry test.

(d) Submission of test results. NIOSH-approved facilities must submit results of spirometry examinations electronically with content as specified in § 37.96(b), pre-test screening checklists, and standardized respiratory assessments within 14 calendar days of testing a miner.

(e) Records retention. On-site records of the results will include spirometry examination reports and retention of all spirometry examinations, pre-test checklists, and standardized respiratory assessment results in electronic or printed format until notification to delete or render the information inaccessible, as described in § 37.100(b)(6)(ii), is received from NIOSH.

§ 37.96 Spirometry interpretations, reports, and notifications.

(a) Interpretation of spirometry examinations. Interpretations will be carried out by physicians or other qualified health care professionals with expertise in spirometry who have all required licensure and privileges to provide this service in their State or Territory. Interpretations must be carried out using procedures and

criteria consistent with recommendations in the ATS Technical Standards: Spirometry in the Occupational Setting, pp. 987-990, and the ATS/ERS Interpretative Strategies for Lung Function Tests, p. 950, p. 956 including Table 5, and p. 957 including Table 6 (both incorporated by reference, see § 37.97).

(b) Spirometry test reports at the facilities._(1)

Spirometry test reports must contain, at a minimum, the miner's age, height, gender, race, and weight, numerical values (FVC, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, FET, and PEF) and volume-time and flow-volume spirograms for all recorded expiratory maneuvers, normal reference value set used, the predicted, percent predicted and lower limit of normal values, miner position during testing (standing or sitting), dates of test and last calibration check, ambient temperature and barometric pressure (volume spirometers), and the technician's unique identification number.

(2) NIOSH will notify the submitting facility when to permanently delete or, if this is not technologically feasible for the spirometry system used, render permanently inaccessible all files and forms associated with a miner's spirometry examination from its electronic and physical files.

(c) Notifying miners of spirometry examination results.

(1) Findings must be communicated to the miner or, if requested by the miner, to the miner's designated physician. The health care professional at the NIOSH-approved facility must inform the miner if the spirometry examination shows abnormal results or if the respiratory assessment suggests he or she may benefit from the medical follow-up or a smoking cessation intervention.

(2) NIOSH will notify the miner of his or her spirometry examination results and the results of a comparison between current and previously submitted spirometry examinations and will advise the miner to contact a health care professional as appropriate based on the results.

(d) Submission of results. Each facility must submit spirometry results and completed forms to NIOSH within 14 days after a miner has received an examination under this subpart. If specified under a facility's approval, it must submit spirometry results and the completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, via electronic transmission. Facilities must utilize a secure internet data transfer

site specified by NIOSH. The transmitted spirometry data files must include a variable length record providing all parameters in the format, content, and data structure described by the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see § 37.97), or an alternate data file that is approved by NIOSH. If electronic transmission of spirometry results is not possible, for example if a facility's spirometer does not provide an approved electronic transfer of spirometry files, then the miner's Spirometry Results Form (Form CDC/NIOSH (M)2.17), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be completed and submitted accompanied by image files documenting the flow-volume and volume time curves for each trial reported on the Results Form. Such facilities must also send a completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16). Data submission to NIOSH by such a facility must be carried out as specified in the facility's approval.

(e) Confidentiality of spirometry examinations.

Individual medical information and spirometry results are considered protected health information under HIPAA and may only be released as specified by HIPAA or to NIOSH as

specified in §§ 37.93 and 37.96 of this subpart. Personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative. To provide on-site back-up and assure complete data transfer, facilities will retain the forms and results (in electronic or paper format) from a miner's examination until instruction has been received from NIOSH to delete the associated files and forms or, if this is not technologically feasible, render the data permanently inaccessible.

§ 37.97 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this subpart, Subpart--Spirometry Examinations, with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at NIOSH, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505. To arrange for an inspection at NIOSH, call 304-285-5749. Copies are also available for

inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibv_locations.html.

(b) American Journal of Respiratory and Critical Care Medicine, American Thoracic Society (ATS), 25 Broadway, 18th Floor, New York, NY 10004. Phone: (800) 635-7181, extension 8065. E-mail: Hope.Robinson@sheridan.com. <http://www.atsjournals.org/action/showHome>:

(1) Standardization of Spirometry; 1994 Update. Official Statement of the ATS, adopted November 11, 1994. American Journal of Respiratory and Critical Care Medicine 152(3):1107-1136, September 1995, into § 37.95(b). This ATS Official Statement is also available at <http://www.thoracic.org/statements/resources/archive/201.pdf>.

(2) Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting ("ATS Technical Standards: Spirometry in the Occupational Setting"). Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, Sigsgaard T, and Weissman DN. American Journal of Respiratory and Critical Care

Medicine 189(8):983-994, April 15, 2014, into §§ 37.92(b) and 37.96(a).

(3) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine, 159(1):179-187, January 1999, into § 37.92(b).

(c) European Respiratory Journal, 442 Glossop Road, Sheffield, S10 2PX, UK. Phone: 44 114 267 28 60; Fax: 44 114 266 50 64. E-mail: info@ersj.org.uk.
<http://erj.ersjournals.com/>.

(1) Standardisation of Spirometry ("2005 ATS/ERS Standardisation of Spirometry"). ATS/ERS Task Force: Standardization of Lung Function Testing. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Crapo R, Enright P, van der Grinten CPM, Gustafsson P, Jensen R, Johnson DC, MacIntyre N, McKay R, Navajas D, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 26(2):319-338, August 2005, into §§ 37.93(b); 37.95(b) and (c); and 37.96(d). The ATS/ERS Standardisation of Spirometry is also available on the ATS website at <https://foundation.thoracic.org/statements/resources/pft/PFT2.pdf>.

(2) Interpretative Strategies for Lung Function Tests ("ATS/ERS Interpretative Strategies for Lung Function Tests"). ATS/ERS Task Force: Standardisation of Lung Function Testing. Pellegrino R, Viegi G, Brusasco V, Crapo RO, Burgos F, Casaburi R, Coates A, van der Grinten CPM, Gustafsson P, Hankinson J, Jensen R, Johnson DC, MacIntyre N, McKay R, Miller MR, Navajas D, Pedersen OF, and Wanger J. European Respiratory Journal 26(5):948-968, November 2005, into § 37.96(a). The ATS/ERS Standardisation of Lung Function Testing is also available on the ATS website at <http://www.thoracic.org/statements/resources/pft/pft5.pdf>.

(3) Standardisation of Lung Function Testing, the Authors' Replies to Readers' Comments ("Standardisation of Lung Function Testing, Replies to Readers"). Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Enright P, van der Grinten C, Gustafsson P, Jensen R, MacIntyre N, McKay RT, Pedersen OF, Pellegrino R, Viegi G, and Wanger J. European Respiratory Journal 36(6):1496-1498, December 2010, into § 37.95(c). The Standardisation of Lung Function Testing, Replies to Readers is also available on the ATS website at <http://www.thoracic.org/statements/resources/pft/clarification-12-2010.pdf>.

20. Add a subpart, titled General Requirements, after Subpart--Spirometry Examinations to read as follows:

Subpart--General Requirements

Sec.

37.100 Coal mine operator plan for medical examinations.
37.101 Approval of plans.
37.102 Transfer of affected miner to less dusty area.
37.103 Medical examination at miner's expense.

§ 37.100 Coal mine operator plan for medical examinations.

(a) Each coal mine operator must submit and receive NIOSH approval of a plan for the provision of chest radiographs, occupational histories, spirometry examinations, and respiratory assessments of miners, using the appropriate forms provided by NIOSH.

(1) During the transition from August 1, 2014 until the time when spirometry facilities are approved by NIOSH, any person becoming a coal mine operator on or after August 1, 2014, or any coal mine operator without an approved plan as of that date must submit a plan within 60 days that provides for chest radiographs and occupational histories.

(2) Coal mine operators with previously approved plans for only chest radiographs and occupational histories, or

with plans developed pursuant to paragraph (a)(1) of this section, will be notified by MSHA when the plans must be amended to include spirometry examinations and respiratory assessments. Amendments must be submitted to NIOSH within 60 days of MSHA's notification.

(b) The coal mine operator's plan must include:

(1) The name, address, and telephone number of the operator(s) submitting the plan;

(2) The name, MSHA identification number for respirable dust measurements, and address of the mine included in the plan;

(3) The proposed beginning and ending date of the 6-month period(s) for voluntary radiography and spirometry examinations (see § 37.3(a) and § 37.92(a)), the estimated number of miners to be given or offered examinations during the 6-month period under the plan, and a roster specifying the names and current home mailing addresses of each miner covered by the plan;

(4) The name and location of the approved X-ray and spirometry facility or facilities, and the approximate date(s) and time(s) of day during which the radiographs and spirometry tests will be given to miners to enable a determination of whether the examinations will be conducted at a convenient time and place;

(5) If a mobile medical examination facility is proposed to provide some or all of the surveillance tests specified in paragraph § 37.100(a), the plan shall provide that each miner be given adequate notice of the opportunity to have the examination and that no miner shall have to wait for an examination more than 1 hour before or after his or her work shift. In addition, the plan shall include:

(i) The number of change houses at the mine.

(ii) One or more alternate non-mobile approved medical examination facilities for the reexamination of miners and for the mandatory examination of miners when necessary [see §§ 37.3(b) and 37.92(b)], or an assurance that the mobile facility will return to the location(s) specified in the plan as frequently as necessary to provide for medical surveillance examinations in accordance with these regulations.

(iii) The name and location of each change house at which examinations will be given. For mines with more than one change house, the examinations shall be given at each change house or at a change house located at a convenient place for each miner.

(6) Assurances that:

(i) The operator will not solicit a physician's spirometric, radiographic or other findings concerning any miner employed by the operator,

(ii) Instructions have been given to the person(s) giving the examinations that duplicate spirograms or copies of spirograms (including copies of electronic files) and radiographs or copies of radiographs (including, for digital radiographs, copies of electronic files) will not be made, and to the extent that it is technically feasible all related electronic files must be permanently deleted from the facility records or rendered permanently inaccessible following the confirmed transfer of such data to NIOSH, and that (except as may be necessary for the purpose of this part) the physician's spirometric, radiographic and other findings, as well as the occupational history and respiratory assessment information obtained from a miner will not be disclosed in a manner that would permit identification of the individual with their information, and

(iii) The spirometry and radiographic examinations will be made at no charge to the miner.

(c) Operators may provide for alternate spirometry or radiography facilities in plans submitted for approval.

(d) The change of operators of any mine operating under a plan approved pursuant to § 37.101(a) shall not affect the plan of the operator which has transferred responsibility for the mine. Every plan shall be subject to revision in accordance with paragraph (e) of this section.

(e) The operator must advise NIOSH of any change in its plan. Each change in an approved plan is subject to the same review and approval as the originally approved plan.

(f) The operator must promptly display in a visible location on the bulletin board at the mine its proposed plan or proposed change in plan when it is submitted to NIOSH. The proposed plan or change in plan must remain posted in a visible location on the bulletin board until NIOSH either grants or denies approval of it at which time the approved plan or denial of approval must be permanently posted. In the case of an operator who does not have a bulletin board, such as an operator that is a contractor, the operator must otherwise notify its employees of the examination arrangements. Upon request, the contractor must show NIOSH written evidence that its employees have been notified.

(g) Upon notification from NIOSH that sufficient time has elapsed since the previous period of examinations, the operator will resubmit its plan for each of its coal mines

to NIOSH for approval for the next period of examinations (see §§ 37.3(a)(2) and 37.92(a)). The plan must include the proposed beginning and ending dates of the next period of examinations and all information required by paragraph (b) of this section.

§ 37.101 Approval of plans.

(a) If, after review of any plan submitted pursuant to this subpart, NIOSH determines that the action to be taken under the plan by the operator meets the specifications of this subpart and will effectively achieve its purpose, NIOSH will approve the plan and notify the operator submitting the plan of the approval. Approval may be conditioned upon such terms as the Secretary deems necessary to carry out the purpose of § 203 of the Act.

(b) Where NIOSH has reason to believe that it will deny approval of a plan NIOSH will, prior to the denial, give notice in writing to the operator(s) of an opportunity to amend the plan. The notice must specify the ground(s) upon which approval is proposed to be denied.

(c) If a plan is denied approval, NIOSH will advise the operator(s) in writing of the reasons for the denial.

§ 37.102 Transfer of affected miner to less dusty area.

(a) Any miner who, in the judgment of NIOSH, has evidence of the development of pneumoconiosis, must be afforded the option of transferring from his or her position to another position in an area of the mine where the concentration of respirable dust in the mine atmosphere is in compliance with the MSHA requirements in Part 90 of title 30, Code of Federal Regulations. A classification of one or more of the miner's chest radiographs as showing category 1 (1/0, 1/1, 1/2), category 2 (2/1, 2/2, 2/3), or category 3 (3/2, 3/3, 3/+) simple pneumoconioses, or complicated pneumoconiosis (ILO Classification) will be accepted as such evidence. NIOSH will, at its discretion, also accept other medical examinations provided to NIOSH for review, such as computed tomography scans of the chest or lung biopsies, as evidence of the development of pneumoconiosis.

(b) Any transfer under this section shall be in accordance with the procedures specified in 30 CFR part 90.

§ 37.103 Medical examination at miner's expense.

Any miner who wishes to obtain a medical examination at the miner's own expense at an approved spirometry or radiography facility and to have the complete examination submitted to NIOSH may do so, provided that the examination

is made no sooner than 6 months after the most recent examination of the miner submitted to NIOSH. NIOSH will provide interpretation and radiographic classification and reporting of the results of examinations made at the miner's expense in the same manner as if they were submitted under an operator's plan. Any change in the miner's transfer rights under the Act that may result from this examination will be subject to the terms of § 37.102.

Dated: July 30, 2014.

Sylvia M. Burwell,
Secretary.

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